

In the United States Court of Federal Claims

No. 15-972V
(Originally filed: May 1, 2017)
(Re-filed: May 22, 2017)¹

PAUL MONDELLO,

Petitioner,

v.

SECRETARY OF THE
DEPARTMENT OF HEALTH AND
HUMAN SERVICES,

National Childhood
Vaccine Injury Act;
Hepatitis A Vaccine;
Seizure Disorder; Motion
for Review; Causation.

Respondent.

Verne E. Paradie, Jr., Lewiston, ME, for petitioner.

Darryl R. Wishard, Senior Trial Attorney in the Torts Branch of the Civil Division, Department of Justice, Washington, DC, with whom are, *Benjamin C. Mizer*, Assistant Attorney General, *C. Salvatore D'Alessio*, Director, *Catherine E. Reeves*, Deputy Director, for respondent.

OPINION

BRUGGINK, *Judge.*

This is a case brought under the National Childhood Vaccine Injury Act for compensation for injuries allegedly sustained after the administration of a hepatitis A vaccination received by petitioner, Paul Mondello, on November

¹ Publication of this opinion was deferred pending the parties' review for redaction of protected information. *See* Rules of the Court of Federal Claims, App. B, Rule 18(b). Neither party submitted proposed redactions. Accordingly, the opinion appears below in full.

15, 2013.² The petition alleges that the vaccine caused him to develop a seizure disorder and related neurological symptoms and deficits. The Special Master dismissed the petition for lack of evidence of causation. Petitioner has appealed that decision in a motion for review to this court. The motion is fully briefed, and oral argument is deemed unnecessary. Because there was some evidence evincing a theory of causation, we reverse the Special Master's decision and remand for further proceedings consistent with this opinion.

BACKGROUND

I. Factual History

Petitioner was born on October 2, 1943. He served in the Vietnam War and was honorably discharged after receiving a severe blow to the head and crush injuries to his knees and back. Afterwards, he was treated at Togus Veterans Administration Hospital ("Togus") for hypertension, post-traumatic stress disorder ("PTSD"), osteoarthritis, hearing loss, gastroesophageal reflux disorder, migraines, abnormal glucose, chronic back pain, and chronic hepatitis. Petitioner's medical history included Agent Orange exposure, traumatic brain injury, crush injuries to the knees and back, and Stevens-Johnson syndrome from taking hydrochlorothiazide.

Petitioner was admitted to a rehabilitation program at Togus for alcohol and daily cannabis dependence in October 2013. He also regularly used benzodiazepine to treat panic attacks and anxiety, but reported having discontinued its use during this time period. He was also prescribed cyproheptadine, an antihistamine, for his PTSD-related symptoms during this admission at Togus.³

² Petitioner was administered a Twinrix hepatitis A and B vaccination, but most of petitioner's records refer only to hepatitis A vaccination as the cause of his seizure disorder.

³ Cyproheptadine is an anti-histamine used to relieve allergy symptoms such as sneezing, itching, watery eyes, runny nose, and other symptoms of allergies. It is also used to treat nightmares in those suffering from symptoms of PTSD. Its side effects are reported as including dizziness, blurred vision, fatigue, and palpitations. Overdosage can result in hallucinations, convulsions, and central nervous system ("CNS") depression. It is thought to have additive effects with
(continued...)

On November 15, 2013, petitioner visited Togus for a follow up to his rehabilitation. Records from that visit noted that he reported not having had alcohol for 36 days and that his medications included cyproheptadine. It was during this visit when petitioner received a Twinrix hepatitis A and B vaccine.

A week later, on November 22, 2013, petitioner was admitted to St. Joseph's Hospital during an episode of active seizures and an altered state of consciousness. He was actively seizing upon arrival at the hospital. His wife reported that he had not been feeling well since receiving the Twinrix vaccination and that he suffered from nausea, vomiting, and poor appetite. She also stated that petitioner had taken cyproheptadine for the first time at around 4:00 pm that day because he was experiencing tremors, anxiety, and chest palpitations. She recalled that he became confused shortly thereafter and began hallucinating and talking about flashes of light at approximately 5:00 pm, which was about the time petitioner had the seizures.

Upon arrival at the hospital, petitioner had a Glasgow Coma Scale ("CGS") score of 7; he was intubated and administered diazepam.⁴ He underwent a CT scan of his head, which was normal. He tested positive for benzodiazepines and marijuana. Petitioner was then transferred to the emergency department at Eastern Main Medical Center ("EMMC") with an assessment of "generalized status epilepticus of unknown cause," and noting that petitioner was a longstanding alcoholic but had been sober for 46 days, with no prior history of seizures. *Mondello v. Sec'y of HHS*, No. 15-972V, Slip. Op. at 3 n.4. (Fed. Cl. Spec. Mstr. Nov. 15, 2016) (quoting Pet.'s Ex. 1 at 31).

At EMMC, petitioner underwent a battery of diagnostic tests. An EEG showed "diffuse right-sided slowing," "transient periodic right lateralized discharges involving frontal area," and "intermittent spikes throughout the record involving right frontal area." *Id.* (quoting Pet.'s Ex. 5 at 1394). An MRI revealed "no acute or malignant intracranial process," with "moderate burden

³(...continued)

alcohol and other CNS depressants. *Mondello v. Sec'y of HHS*, No. 15-972V, Slip. Op. at 3 n.4. (Fed. Cl. Spec. Mstr. Nov. 15, 2016) (unpublished order dismissing petition).

⁴ GCS is used to measure the severity of an acute brain injury, where a score of 3 is the most severe and a score of 15 is the least severe.

of white matter signal changes” and “mild diffuse cerebral volume loss.” *Id.* (quoting Pet. Ex. 5 at 1400). Treating physicians were uncertain of the clinical significance of these results.

While at EMMC, petitioner was treated by a neurologist, Dr. Bourque. She ordered a lumbar puncture of Mr. Mondello because of the possibility that he may have had an aseptic meningitis related to the vaccination. The lab test was negative for meningitis. Dr. Bourque prescribed Keppra, an anti-seizure medication, and petitioner was discharged from EMMC on November 27, 2013, with a diagnosis of new-onset seizure, with delirium and hyponatremia.⁵ The discharge summary reflected no specific cause but noted that his condition was consistent with alcohol withdrawal and the possibility of benzodiazepine withdrawal. The summary also reported that the hepatitis A vaccine’s effects, along with other medications and health problems were all of note as well as possibly having a causal link.

Through December 2013, petitioner received physical therapy at home. On January 9, 2014, he sought care at Mayo Practice Associates (“Mayo”) after complaining of left trapezius strain and knee pain. The Mayo record listed cyproheptadine as one of his allergies, with a reaction of seizures and confusion.

On January 30, 2014, petitioner met with Dr. Bourque for a follow-up visit. Her notes from that occasion record that she had initially treated him at EMMC on November 2013 for a new onset of seizures. Those notes further reflected that he had been administered a hepatitis A vaccine one week prior to his hospitalization and that he reported experiencing nausea, vomiting, headache, and chills during the intervening week. Further stated was that, on the day of hospitalization, he took four milligrams of cyproheptadine for the first time in his life. His wife informed doctors that within 20-30 minutes of taking cyproheptadine, he started experiencing visual hallucinations. She then left the room to call 911, and when she came back, found him seizing.

Dr. Bourque’s notes also record that petitioner had not suffered any further severe headaches, seizures, fevers, or lateral weakness since his discharge from EMMC, and had done well on Keppra. Overall, his mental

⁵ Hyponatremia is a condition when the level of sodium in the blood becomes abnormally low, which can cause nausea, vomiting, headache, confusion, fatigue, muscle weakness, and seizures.

status had returned close to baseline, although his wife stated that he occasionally had episodes during which his ability to give directions seemed impaired. Dr. Bourque suggested that he see a neuropsychologist for a baseline assessment of cognitive strengths and weaknesses.

On April 7, 2014, petitioner again saw Dr. Bourque for another follow-up appointment. Dr. Bourque again recorded petitioner's history regarding the administration of the vaccine, subsequent illness, and presentation at the hospital for seizures a week later. Notes from the April 7 visit indicate that Mr. Mondello had not experienced any more seizures nor spells of confusion, but had started drinking again intermittently. These notes also reflect that petitioner was again tested with an EEG on February 24, 2014, which returned normal results. During this visit, Dr. Bourque also discussed with petitioner tapering off Keppra. She warned, however, that there was a potential for recurrent seizures. She also mentioned the possibility of switching from Keppra to Trileptal, but Mr. Mondello was not interested in pursuing any of these options because it would have meant that he would have had to stop driving for three to six months, and he had been tolerating Keppra better.

Almost a year later, on March 20, 2015, petitioner was treated by Dr. Bourque for a possible seizure despite the anticonvulsants after petitioner had, of his own initiative, reduced his Keppra dosage by a quarter for two days. He reported returning to the full dose during the weekend prior to this visit, but that on the following Tuesday he experienced an unusual 30-second episode of facial distortion and general unresponsiveness without limb shaking, automatisms, or lip smacking. In her records, Dr. Bourque again noted the history of hepatitis A vaccine a week prior to the initial 2013 seizures and the first dose of cyproheptadine shortly before the seizure onset. She advised that petitioner return to his regular Keppra dosage and that they would discuss tapering off it again later that fall.

Petitioner's next visit to Dr. Bourque was on October 2, 2015. He had suffered no further seizures after the March 20, 2015 appointment. Dr. Bourque noted that:

[p]etitioner continues to have a history of hospitalization with what was suspected to be possibly a provoked seizure in 2013, but with an abnormal EEG at that time. When he tried taking himself off Keppra earlier this year, he had what was an atypical spell that may have represented a seizure, so we will continue on

Keppra.

Pet's Ex. 7 at 1451.

On March 18, 2016, petitioner returned for his final visit to Dr. Bourque regarding his seizures. Petitioner reported to Dr. Bourque that, although he had not experienced any further seizures, he was experiencing some cognitive difficulties. The doctor's notes again recited his history beginning with the 2013 hepatitis vaccine and subsequent hospitalization. These notes included the opinion that the 2013 seizures were the result of a combination of petitioner's being unwell from the hepatitis A vaccine and having taken cyproheptadine. Her diagnosis for petitioner's cognitive trouble was that it was likely the result of a combination of his previous head injuries, alcoholism, chronic pain, and untreated psychiatric illness. Petitioner was discharged from neurological care on this date.

II. Procedural History

On September 3, 2015, petitioner timely filed a petition for compensation under the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 to-34 (2012) ("Vaccine Act"). He eventually, after twice supplementing, filed all of his relevant medical records. Respondent subsequently filed a report, as required by Vaccine Rule 4(c)(1), recommending against compensation. Respondent argued that petitioner had failed to satisfy the causation standard articulated in *Althen v. Sec'y of HHS.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005), and further averred that "the more likely cause of petitioner's seizure onset was the resultant side effect of his first dose of cyproheptadine." Resp't Rule 4(c) Report at 6.

The Special Master reviewed the petitioner's records and ordered him to file an expert report because his records did not provide a medical theory causally connecting the vaccine at issue with petitioner's injury. *Mondello v. Sec'y of HHS*, No. 15-972V (Fed. Cl. Spec. Mstr. May 19, 2016). Petitioner instead informed the court that he had filed all of his relevant medical records and would not be filing an expert report. Then, on August 1, 2016, petitioner filed a 10-page motion asking for a decision on the merits based on the record as it was, or, in the alternative, for an evidentiary hearing.

In his motion for a ruling on the record, petitioner relied most on Dr. Bourque's treatment records, arguing that they contained the doctor's opinion

that the vaccination was a substantial factor in bringing about his seizure disorder. Petitioner acknowledged that he had not submitted an expert opinion as to “the exact biological mechanism” causing his illness but argued that none was necessary given the temporal relationship between the onset of symptoms after the vaccination, medical literature in the record, and Dr. Bourque’s “opinion that the vaccination was a contributing factor to Mr. Mondello’s condition.” Pet.’s Mot. for Ruling on the R. 4. He further argued that requiring proof of a specific biological mechanism was inconsistent with the purpose of the Act and imposed an impermissibly high evidentiary standard on claimants.

After confirming that petitioner understood the ramifications of a ruling on the record as opposed to a dismissal decision, the Special Master issued a decision on November 15, 2016, dismissing the petition because petitioner “failed to produce preponderant evidence that the hepatitis A vaccination [was] responsible for his condition.” *Mondello*, Slip. Op. at 9. The Special Master reviewed Dr. Bourque’s records but disagreed with petitioner as to their contents. She found that they did not offer any specific causative theory of how Mr. Mondello’s seizures were caused by the vaccine and that the doctor did not otherwise opine that the seizure would not have occurred in the absence of the vaccination. *Id.* at 8. The Special Master stated that the medical records were only a detailed recitation of the facts related to petitioner’s hospitalization and his symptoms since November 2013. She further found that petitioner’s list of other morbidities, along with his first dose of cyproheptadine, undermined the allegation that the hepatitis A vaccine was more likely than not the cause of, or a substantial factor in causing, the seizure disorder. Without a sufficient medical opinion on causality or other plausible medical theory in support of his claim, the Special Master held that she was constrained by the case law to dismiss the petition for lack of evidence of causation. Petitioner filed a motion for review of this decision on December 14, 2016, and respondent filed a response to the motion on January 11, 2017.

DISCUSSION

In his motion for review, petitioner asserts that the Special Master erred in ignoring the opinion of the treating physician and should not have penalized petitioner for not hiring an expert to opine on causation. Petitioner argues that Dr. Bourque’s records contained an opinion that the hepatitis vaccination was a substantial causative factor in the seizures that he suffered. That Dr. Bourque did not posit a theory of the precise biological mechanism that caused the

vaccine to injure plaintiff is not dispositive, according to petitioner, particularly given her more general opinion that it was a co-factor in causing the injury and the medical literature that he argues provides an etiological link between the vaccine and the seizures suffered.

By emphasizing the fact that petitioner did not submit an outside expert opinion and by not taking account of the relevant medical and scientific literature, the Special Master impermissibly raised petitioner's burden of providing a medical theory beyond that of biological plausibility—all that is required by the Vaccine Act—argues petitioner. As to a temporal link between the vaccine and the injury, petitioner contends that his medical records show that he became ill immediately after being vaccinated and that he remained so until he was hospitalized with the seizures. The cyproheptadine posited as a cause by the government is a red herring because he was already sick before taking it; he asserts that he would not have taken it had he not been ill for a whole week following the vaccination.

The government responds that the Special Master appropriately considered all the evidence and followed applicable legal precedent in determining that petitioner failed to meet his burden of proving causation. Respondent agrees with the Special Master that Dr. Bourque's records do not contain any specific medical theory regarding how the hepatitis A vaccine could cause the seizures, which is insufficient to meet the standard of proof, it argues. Respondent also offers petitioner's other medical and substance abuse problems as factors undermining his claim that the vaccine was "more likely than not" the cause of his seizure onset.

Respondent further contends that petitioner misinterprets the law regarding the significance of the opinions of treating physicians, especially when, as in this case, they do not posit an actual theory of biological causality or unequivocally state that the cause of the injury was the vaccine. Finally, in response to petitioner's point that the Special Master ignored his medical literature aimed at the first prong—a medical theory of causation—the government argues that the special masters are not required to discuss every piece of evidence present in the record as long as the decision is clear that they have considered all of the parties' evidence and arguments.

I. Jurisdiction And Standard Of Review

We have jurisdiction pursuant to 42 U.S.C. § 300aa-12 to hear appeals

of decisions by the Office of Special Masters granting or denying compensation. In reviewing a decision rendered by a Special Master, we may: (1) uphold the findings of fact and conclusions of law; (2) set aside any of the findings of fact or conclusions of law “found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;” or (3) remand the petition to the special master for further action in accordance with the court’s direction. 42 U.S.C. § 300aa-12(e)(2)(A)-(C).

In deciding a motion for review, we do not “re-weigh the factual evidence, or . . . assess whether the special master correctly evaluated the evidence” nor do we “examine the probative value of the evidence or the credibility of the witnesses. These are all areas within the purview of the fact finder.” *Lampe v. Sec’y of HHS*, 219 F.3d 1357, 1360 (Fed. Cir. 2000). This means that if the Special Master has considered the relevant evidence of the record, drawn plausible inferences, and articulated a rational basis for the decision, the court reviewing the Special Master’s decision is compelled to uphold the findings as neither arbitrary nor capricious. *Cedillo v. Sec’y of HHS*, 617 F.3d 1328, 1338 (Fed. Cir. 2010).

To receive compensation for a vaccine related injury under the Vaccine Act, the petitioner bears the burden of proving by a preponderance of the evidence the elements required to entitle him or her to relief, which are listed in 42 U.S.C. § 300aa-11(c)(1). For an “off table” injury case, as here, the petitioner has the burden to prove that the vaccine “caused” the illness, disability, injury, or condition. *Id.* § 300aa-11(c)(1)(C)(ii)(I). This mean that a petitioner must show by preponderant evidence both that the vaccination was a “substantial factor” in causing the illness, disability, injury, or condition and that the harm would not have occurred in the absence of the vaccination. *Shyface v. Sec’y of HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). In order to establish that the vaccine was a substantial factor in causing the injury, petitioner must show: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a proximate temporal relationship between the vaccination and injury. *Althen*, 418 F.3d at 1278. The same evidence may be used to establish multiple of the *Althen* prongs. *Capizzano v. Sec’y of HHS*, 418 F.3d 1317, 1326 (Fed. Cir. 2006).

The first prong of the *Althen* test focuses on whether the vaccine in question can cause the type of injury alleged. *Pafford v. Sec’y of HHS*, 451 F.3d 1352, 1356 (Fed. Cir. 2006). This inquiry allows medical opinion as

proof, even without scientific studies in medical literature providing “objective confirmation” of medical plausibility. *Althen*, 418 F.3d at 1279. The second prong is concerned with whether the vaccine did cause petitioner’s injury, which involves the presentation of a “reputable medical or scientific explanation.” *Id.* It, like the first prong, however, does not require proof of a “specific biological mechanism[.]” *Capizzano*, 440 F.3d at 1325 (citing *Knudsen*, 35 F.3d at 549). Circumstantial evidence may also be cited to meet the test. *Id.* (citing *Althen*, 418 F.3d at 1280). Finally, the third prong demands a showing that the injury’s onset occurred “within a time frame for which, given the medical understanding of the disorder’s etiology, it is medically acceptable to infer causation-in-fact.” *De Bazan v. Sec’y of HHS*, 539 F.3d 1347, 1352 (Fed. Cir. 2008).

If the petitioner can meet the causation standard, he has established a *prima facie* case, and the burden shifts to the government to prove “[by] a preponderance of the evidence that the [petitioner’s injury] is due to factors unrelated to the administration of the vaccine described in the petition.” 42 U.S.C. § 300aa-13(a)(1)(B). *Walther v. Sec’y of HHS*, 485 F.3d 1146, 1151 (Fed. Cir. 2007).

II. Dr. Bourque’s Medical Records Offer An Opinion Of A Causal Link Between The Hepatitis A Vaccine And Petitioner’s Seizure Disorder

The Vaccine Act requires petitioners to provide, at a minimum, proof in the form of medical records or by medical opinion. 42 U.S.C. § 300aa-13(a)(1) (requiring proof of causation “by medical records or by medical opinion). Medical records “warrant consideration as trustworthy evidence” because these records are “generally contemporaneous to the medical events,” and “accuracy has an extra premium.” *Cucuras v. Sec’y of HHS*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). The medical records and opinions of treating physicians are “quite probative” because “treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury. *Capizzano*, 440 F.3d at 1326.

Here, the Special Master considered the records of Dr. Bourque but found them “not [to] offer any opinions regarding causation between Mr. Mondello’s receipt of the hepatitis A vaccine and the onset of seizures.” *Mondello*, Slip. Op. at 7. She found that the doctor’s records provided only a history of events prior to and post-vaccination. Thus, petitioner’s choice not

to provide an expert opinion causally linking the vaccine to the seizures or other symptoms suffered by petitioner was fatal to his claim. “Ultimately, petitioner has failed to provide either a sufficient medical opinion or plausible medical theory in support of his claim that the hepatitis vaccine caused or significantly contributed to his seizures.” *Id.* at 8. Further, the Special Master decided that the petitioner’s prior medical history (“co-morbidities”), the fact that he took the particular antihistamine just prior to the onset of seizures, and his record of having used CNS depressants contemporaneous with the antihistamine undermined any evidence suggesting a “more likely than not” link between the vaccine and the injuries suffered by petitioner. *Id.*

We cannot go so far. Most of what is contained in Dr. Bourque’s notes and records is, as stated by the Special Master, a recitation of Mr. Mondello’s medical history, centering on his 2013 seizure episode. It is of note, however, that in each record of treatment, Dr. Bourque is careful to continue to point out the close temporal relationship between the administration of the Twinrix vaccine and the onset of seizures. Also of importance to her is the fact that petitioner was sick almost immediately after the vaccination, even prior to taking the cyproheptadine. Most important, however, is the record from petitioner’s final visit to Dr. Bourque in March 2016. It states, “Impression and Plan: Mr. Mondello continues to have a history of hospitalization in November 2013 for suspected provoked seizure, which was likely a combination of being unwell from a hepatitis A vaccine and the compilation of cyproheptadine” Pet.’s Ex. 9 at 1486. That is an opinion regarding causation. As stated in several of Dr. Bourque’s notes from earlier visits, she viewed the seizure episode in 2013 as provoked, i.e., not caused by an already existing medical condition suffered by petitioner. Her notes from petitioner’s final visit indicate her opinion that the provocation for the seizure was a combination of the illness suffered as a result of the vaccine and cyproheptadine. We make no judgment regarding its weight or sufficiency to meet petitioner’s burden under the Vaccine Act, but we cannot agree that Dr. Bourque provided no opinion regarding medical causation of the seizure episode.

Further, there are other pieces of evidence submitted by petitioner that arguably lend some support to his claim. He submitted two pieces of medical literature along with Vaccine Information Sheets and a Twinrix package insert in support of his motion for a decision on the record. The first is a study entitled “A case-control study of serious autoimmune adverse events following hepatitis B immunization” by David and Mark Geier. In it, the authors reported that they found an increased incidence of serious autoimmune disorders

following administration of the hepatitis B vaccine to adults as compared to a control group administered only a tetanus vaccine between the years of 1990-2004. Pet.'s Ex. 13. The second study presented by petitioner is entitled "Population-Level Evidence for an Autoimmune Etiology of Epilepsy" by Mei-Sing Ong, *et al.* Pet's Ex. 14. This study found an increased risk of epilepsy, a seizure disorder, among non-elderly patients with autoimmune diseases. Petitioner suggests that these two studies, read together, provide evidence of a biological causation between the hepatitis vaccine and the seizures experienced by plaintiff. Further, the vaccine information sheets and Twinrix package insert are cited by petitioner to support the idea that the illness he experienced during the week after the vaccination but before the seizure is consistent with the frequent side effects listed for the vaccine that he was administered.

Although the Federal Circuit makes clear that claimant need not produce medical literature or epidemiological evidence to establish causation under the Vaccine Act, where such evidence is submitted, the Special Master can consider it to determine whether a vaccine in question did in fact cause a particular injury. *See Althen*, 418 F.3d at 1280; *see also Capizzano*, 440 F.3d 1317 at 1324. Petitioner, however, must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case, although the explanation need only be "legally probable, not medically or scientifically certain." *Knudsen v. Sec'y of HHS*, 35 F.3d 543, 548-49 (Fed. Cir. 1994).

Here, petitioner submitted two pieces of medical literature. The first found an increased incidence of serious autoimmune adverse effects of hepatitis B vaccination. Pet.'s Ex. 13 (David A. & Mark R. Geier, *A Case-Control Study of Serious Autoimmune Adverse Events Following Hepatitis B Immunization*, *Autoimmunity*, June 2005, at 295). The other evaluated how the risk of serious seizure disorders increases in patients with autoimmune disease. "[S]pecific autoimmune causes, typically associated with autoantibodies, have been increasingly identified in a subset of previously idiopathic seizure disorders. In some of these situations, seizures are associated with other neurologic manifestation; in others, they are the only sign of neurologic autoimmunity." Pet.'s Ex. 14 (Mai-Sing Ong, Isaac S. Kohane, Tianxi Cai, Mark P. Gorman, Kenneth D. Mandl, *Population-Level Evidence for an Autoimmune Etiology of Epilepsy*, *JAMA Neurology*, 2014, at 569.). This evidence does not appear to have been considered in the decision below.

Respondent cites to *Snyder v. Sec'y of HHS*, 36 Fed. Cl. 461, 466 (1996) and *Murphy v. Sec'y of HHS*, 23 Cl. Ct. 726, 734 n.8 (1991), for the proposition that a special master need not discuss every piece of evidence in the record so long as her decision makes clear that she fully considered petitioner's relevant evidence and arguments. The government argues that nothing cited by petitioner provides a reputable medical theory of vaccine causation, either alone or when considered with Dr. Bourque's medical records, and thus the Special Master did not err by not specifically calling this fact out in her decision.

We cannot say on review whether this evidence ought to have changed the Special Master's decision nor do we make an attempt to consider whether it is sufficient to provide some proof of etiology. It may well be that expert testimony would be necessary to elucidate the question of whether these studies lend any support to petitioner's claim. We also cannot say, however, that, on their face, they are irrelevant to petitioner's claim for compensation. Nor can we say that we are confident that the Special Master considered them before rejecting the petition as insufficiently positing a theory of causation.

III. Possible Legal Error Assigning Burden to Petitioner to Eliminate Alternative Causes

Finally, the Special Master concluded that the petitioner's comorbidities and the coincidence of other substances in his blood prior to the seizure episode, when viewed along with the lack of a medical theory of causation, made it impossible for petitioner to show that the hepatitis vaccination is "more likely than not" the cause of, or a substantial factor in causing, the seizures that occurred on November 22, 2013. *Mondello*, Slip Op. at 8. Although it is not clear precisely what weight she was assigning petitioner's other medical problems and the relationship between the other substances and the seizures, those were cited as factors in denying petitioner's claim.

The Vaccine Act provides that, when there are multiple independent potential causes, and petitioner has met his burden on causation, the Secretary then has the burden to prove, also by preponderance of evidence, that the vaccination in question did not cause the harm or the injury was in fact caused by factors unrelated to the vaccine. *Walther*, 485 F.3d at 1151. Here, Dr. Bourque opined that it was likely a combination of the vaccine-caused illness and the cyproheptadine that provoked petitioner's seizures. The Act only

requires a showing of “but for” causation and that the vaccine was a “substantial factor,” not that the vaccine was the only cause. Thus the coincidence of another potential causal agent is not fatal to a claim under the Act. If petitioner meets its burden on causation, then it is the government’s burden to prove that some other cause is to blame, not petitioner’s to disprove it. To the extent the Special Master assigned the burden of eliminating alternative independent potential causes to petitioner, we conclude that she erred.

CONCLUSION

Because the record contains at least some evidence suggesting a theory of causation, we find that the Special Master erred in her conclusion that petitioner’s claim had to be dismissed for not providing any evidence of a theory of causation. Further, to the extent that petitioner was assigned the burden of disproving alternate causes, that was error. We make no findings regarding the sufficiency of Dr. Bourque’s opinion nor the medical literature submitted. That is left to the Special Master on remand. Accordingly, the following is ordered:

1. Petitioner’s motion for review of the Special Master’s November 15, 2016 decision is granted.
2. This case is hereby remanded to the Special Master for further proceedings consistent with this opinion.

s/Eric G. Bruggink
ERIC G. BRUGGINK
Senior Judge